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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,291	08/17/2001	Gary L. Cantrell	MRD/53	4770
26875	7590	11/03/2004	EXAMINER	
WOOD, HERRON & EVANS, LLP			JONES, DAMERON L	
2700 CAREW TOWER				
441 VINE STREET			ART UNIT	PAPER NUMBER
CINCINNATI, OH 45202			1616	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,291	CANTRELL ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 8/18/04 & 9/28/04.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 31-50, 52, 53 and 55-80 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) _____ is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 31-50, 52, 53, and 55-80 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges the amendment filed 8/18/04 wherein claims 1-28 and 30 are canceled; claims 29, 31, 32, and 34-36 are amended; and claims 48-67 are added.

2. The Examiner acknowledges the amend filed 9/28/04 wherein claims 1-30, 51, and 54 are canceled; claims 31, 32-38, 48, 50, 55, and 67 are amended; and claims 68-80 are added.

Note: Claims 31-50, 52, 53, and 55-80 are pending.

COMMENTS/NOTES REGARD THE AMENDMENT

3. Due to the amending of the claims to incorporate specific lamellar structure limitations that were not present in the originally filed claims, the following action is necessary.

RESTRICTION INTO GROUPS

4. The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list

individually. For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121.

LAMELLAR STRUCTURES IN COMBINATION WITH THE VARIABLE A1

- (1). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is CH₃-(CH₂)_e-X and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (2). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is CH₃(CF)_e-X and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (3). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is CF₃-(CF₂)_e-X and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (4). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is CF₃-(CF₂)f-O-CH₂)g-X and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (5). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is CH₃-(CH₂)f-S-(CH₂)g-X and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (6). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is CH₃-(CH₂)f-S-S-(CH₂)g-X and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(7). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)_g\text{CO}_2(\text{CH}_2)_h-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(8). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)_f\text{CONH}(\text{CH}_2)_g-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(9). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)_f\text{NHCON}(\text{CH}_2)_g-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(10). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)\text{FOCONH}(\text{CH}_2)_g-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(11). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)_f\text{NH}(\text{CH}_2)-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(12). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)_f\text{N}[(\text{CH}_2)_g]-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

- (13). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)^f\text{SO}(\text{CH}_2)^g-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (14). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)^f\text{SO}_2(\text{CH}_2)^g-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (15). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-(\text{CH}_2)^m\text{NH}(\text{CH}_2)^f\text{CO}_2(\text{CH}_2)^g-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (16). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is $\text{CH}_3-[(\text{CH}_2)^f]_2\text{N}(\text{CH}_2)^n\text{CONH}(\text{CH}_2)^h-\text{X}$ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (17). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is salts of docosanoic acid and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.
- (18). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is salts of tetracosanoic acid and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(19). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is hexacosanoic acid and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(20). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is octoacosanoic acid and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(21). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is triacontanoic acid and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(22). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is R₂O₂CH₂(CHY)CO₂R and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

(23). Claims 31-50, 52, 53, and 55-80, drawn to a method of targeting an effector molecule wherein the lamellar structure is R₂O₂CCH₂CH₂(CHY)CO₂R₂ and A1 has one specific value which is selected by Applicant as set forth below, classified in 424/9.1.

Note#1: The variable A1 may be selected from the group consisting of CH₃(CH₂)_a-W; CF₃(CH₂)_a-W; CF₃(CF₂)_a-W; CF₃(CF₂)_aCH₂CH₂-W; CH₃(CH₂)_a-O-(CH₂)_b-W; CF₃(CF₂)-O-(CH₂)_b-W; CH₃(CH₂)_a-S-(CH₂)_b-W; CH₃(CH₂)_a-S-S-(CH₂)_b-W; or R₁O₂CCH₂(CHW)CO₂R₁.

Note#2: It should be noted that while the classification is the same, a separate search of the art is necessary for the reasons set forth below.

5. In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex *parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds (i.e., lamellar structures) within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

ELECTION OF SPECIES

6. Where an election of any one of Groups (1) – (23) is made, an election of a single species (or set of species) is further required including identification of each variable associated with the species (i.e., X, R2, Y, X1, B1, B2, L1, L2, A1, A2, W, R1, etc.). In the instant case, upon election of a single species (or set of species), the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds, lamellar structures, which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, but may also include additional compounds which are related. Examination will then proceed on the elected species AND the entire scope of the invention encompassing the elected species. A clear statement of the examined

invention defined by the lamellar structure elected by Applicant will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as Applicant is informed of the full scope of methods involving the lamellar structure in combination with the variable A1 under examination. This will be set forth by reference to the specific *lamellar structure in combination with the variable A1* examined. Should Applicant traverse on the ground that the lamellar structures in combination with the variable A1 are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other groups.

All compounds falling outside the lamellar structure in combination with A1 not encompassed by the election above will be considered to be non-elected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37CFR 1.17(i).

If desired upon election of a single compound, Applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group having a lamellar structure and specific A1 which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

7. Each Group listed above is directed to or involves the compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions, i.e. they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures

are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

8. Each of the groups directed to use of a distinct lamellar structure set forth in Groups (1) – (23) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Methods of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated, 2) the material being used, and 3) the methodology for treatment. If any one or more of these differences exist and are patentably distinct, then the methods are unrelated. In the instant case, the material (lamellar structure in combination with the variable A1) used in the methods of targeting an effector molecule to a target site in a patient are unrelated since the lamellar structure is different for each group.

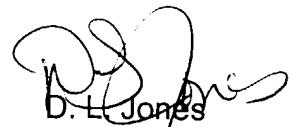
In addition, because of the plethora of possible organized mobile multicomponent conjugates present from the various lamellar structures, A1, A2, L1, L2, B1, B2, W, R1, R2, X, X1, and Y combinations, a serious burden is imposed on the examiner to perform a complete search. Therefore, because of the reasons given above, the restriction set forth is proper and the claims as written impose a serious burden in the examination of this application.

9. Due to the complexity of the restriction requirement, a telephone call was not made to require an election to the above restriction.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1616

October 29, 2004